IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of	)	
	)	
Ramachandran THEMBALATH et al.	)	Group Art Unit: 1615
	)	
Serial No. 10/768,348	)	Examiner: Susan T. Tran
	)	
Filed: January 30, 2004	)	Atty. Dkt. No.: 124907-00107
	)	
For: STABILIZED PAROXETINE HYDROCHLORIDE FORMULATION	)	

DECLARATION OF YATISH KUMAR BANSAL UNDER 37 C.F.R. § 1.132 BY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Yatish Kumar Bansal, an inventor of the above-identified patent application declare as follows:

1. I received Master Degree in Pharmacy from Punjab University, Chandigarh, India in 1983. I pursed my Doctorate of Philosophy in Pharmacy at Birla Institute of Technology & Sciences (BITS), Pilani, Rajasthan, India under Dr. R. N. Saha and submitted my thesis in 2007. I am formulation scientist by training, and presently heading R&D (Formulation), Ipca Laboratories Ltd. I have research experience of more than 22 years from Pharmaceutical Industries in India like Ranbaxy Laboratories Ltd., Dabur pharmaceuticals and Cadila group of companies. I am also an honorary and adjuvant faculty member of BITS, Pilani Rajasthan, India and guided several M. Pharm and B. Pharm students for their research work during Practice School and continuing to do so.

2. The dissolution test presented in this Declaration was collected and performed under my supervision and control in order to demonstrate the dissolution of the formulation described in Example 1 of the specification. 20 and 30 mg tablets were made in accordance with the procedure described in Example 1. Each of the 20 and 30 mg formulations was made in three different batches (AWQ4003F, AWQ4004F, and AWQ4005F for 20 mg formulation; and AWR4003F, AWR4004F, and AWR4003F for 30 mg formulation).

3. The dissolution test was performed in 900 mL of Simulated Gastric Fluid without enzyme, (pH 1.2 Buffer) in accordance with the British Pharmacopoeia specification for Dissolution Test for Tablets and Capsules (Dissolution Test for Solid Dosage Forms (2.9.3)). Each batch was tested before storage ("INITIAL") and after 3 months of storage ("3 MONTHS") at 40 ± 2°C and 75 ± 5% relative humidity (RH), 30 ± 2°C and 65 ± 5% RH, and 25 ± 2°C & 60 ± 5% RH. For each batch at each condition, six samples were obtained. For example, for batch AWQ4003F, six samples were tested at before storage and six samples were tested after 3 months of storage.

4. The drug was assayed using HPLC at the following conditions:

HPLC System - Isocratic

Column - Xterra RP 18 - 50 mm x 4.6 μ m (RP- reverse phase)

Mobile Phase A : Mobile Phase B (80: 20) (make adjustments if necessary)

Mobile Phase A - Water:Tetrahydrofuron:Trifluroacetic acid (90:10:0.5)

Mobile Phase B : Acetonitrile:Tetrahydrofuron:Trifluroacetic acid (90:10:0.5)

Flow rate - about 1.0 ml/min

Injection - 20 μl

Detection: 263 nm, 295 nm

Diluent - Water:Tetrahydofuron (90:10)

5. The following tables shows the result of the dissolution test:

PRODUCT : PAROXETINE TABLETS 20 mg

TABLE 1. SAMPLE STORED AT 40 ± 2°C & 75 ± 5% RH

TEST	SPECIFICATION	BATCH NO.	INITIAL (%)		3 MONTHS(%)	
DISSOLUTION	No less than 75% of stated amount dissolved in 45 minutes	AWQ4003F	96.89	101.8	95.55	92.76
			99.95	100.3	92.87	90.87
			104.4	102.9	93.48	98.88
		AWQ4004F	99.29	98.14	96.61	101.7
			98.29	101.7	91.40	100.1
			102.6	99.44	98.94	96.50
		AWQ4005F	95.71	96.09	103.8	106.0
			103.2	99.91	99.32	106.2
			100.4	97.43	105.0	101.0

TABLE 2. SAMPLE STORED AT 30 ± 2°C & 65 ± 5% RH

TEST	SPECIFICATION	BATCH NO.	INITIAL (%)		3 MONTHS(%)	
DISSOLUTION	No less than 75% of stated amount dissolved in 45 minutes	AWQ4003F	96.89	101.8	90.11	90.40
			99.95	100.3	92.26	90.07
			104.4	102.9	88.56	81.25
		AWQ4004F	99.29	98.14	94.92	92.03
			98.29	101.7	95.77	94.78
			102.6	99.44	91.08	88.10
		AWQ4005F	95.71	96.09	93.57	94.15
			103.2	99.91	95.23	95.00
			100.4	97.43	93.50	94.27

TABLE 3. SAMPLE STORED AT 25 ± 2°C & 60 ± 5% RH

TEST	SPECIFICATION	BATCH NO.	INITIAL (%)		3 MONTHS(%)	
DISSOLUTION	No less than 75% of stated amount dissolved in 45 minutes	AWQ4003F	96.89	101.8	100.8	91.59
			99.95	100.3	99.55	88.19
			104.4	102.9	98.59	98.77
		AWQ4004F	99.29	98.14	95.19	103.2
			98.29	101.7	104.1	98.28
			102.6	99.44	104.4	98.85
		AWQ4005F	95.71	96.09	85.86	85.83
			103.2	99.91	83.71	88.34
			100.4	97.43	89.09	88.96

PRODUCT: PAROXETINE TABLETS 30 mg

TABLE 4. SAMPLE STORED AT 40 ± 2°C & 75 ± 5% RH

TEST	SPECIFICATION	BATCH NO.	INITIAL (%)		3 MONTHS(%)	
DISSOLUTION	No less than 75% of stated amount dissolved in 45 minutes	AWR4003F	96.15	96.03	91.01	100.4
			99.69	98.00	92.22	95.65
			93.74	97.20	92.64	91.65
		AWR4004F	94.51	93.91	94.68	96.69
			96.71	97.58	92.08	92.82
			95.69	89.50	93.70	93.55
		AWR4005F	93.90	101.1	94.83	90.09
			97.10	97.00	96.34	92.99
			95.80	95.40	86.17	94.10

TABLE 5. SAMPLE STORED AT 30 ± 2°C & 65 ± 5% RH

TEST	SPECIFICATION	BATCH NO.	INITIAL (%)		3 MONTHS(%)	
DISSOLUTION	No less than 75% of stated amount dissolved in 45 minutes	AWR4003F	96.15	96.03	102.2	99.92
			99.69	98.00	100.6	101.6
			93.74	97.20	98.20	99.28
		AWR4004 F	94.51	93.91	100.3	99.42
			96.71	97.58	105.1	96.98
			95.69	89.50	99.44	99.73
		AWR4005 F	93.90	101.1	101.8	102.9
			97.10	97.00	102.8	101.8
			95.80	95.40	103.4	99.69

TABLE 6. SAMPLE STORED AT 25 ± 2°C & 60 ± 5% RH

TEST	SPECIFICATION	BATCH NO.	INITIAL (%)		3 MONTHS(%)	
DISSOLUTION	No less than 75% of stated amount dissolved in 45 minutes	AWR4003F	96.15	96.03	101.6	101.5
			99.69	98.00	103.2	103.6
			93.74	97.20	99.84	100.6
		AWR4004 F	94.51	93.91	102.2	98.03
			96.71	97.58	99.19	101.7
			95.69	89.50	101.9	101.1
		AWR4005 F	93.90	101.1	99.47	97.68
			97.10	97.00	99.59	101.1
			95.80	95.40	102.2	99.55

6. From the tables, it is clear that the dissolution of the formulations according to Example 1 in 45 minutes is from about 86 to 100 %. This is within the specification for an immediate release formulation (no less than 75% dissolved in 45 minutes). Importantly, this is much faster than the dissolution profile of Buxton et al. (U.S. Patent No. 5,601,845) (the primary reference cited by the examiner) where 86% dissolution is achieved after 15 hours (Buxton et al., Table 4).

Additionally, this data shows that the formulations of Example 1 are immediate release formulations.

7. All statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

Respectfully submitted,

Date: 26th July 2007

Yatish Kumar Bansal